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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/510,371
Filing Date: October 05, 2004
Appellant(s): PETEREIT ET AL.

Thomas M. Cunningham
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 24, 2007 appealing from the Office action mailed September 26, 2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,804,632	Haddleton et al.	9-1998
6,225,401	Rehmer et al.	5-2001

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-12 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable as obvious over Haddleton et al. (U. S. Patent 5,804,632) in view of Rehmer et. Al (U. S. Patent 6,225,401).

With regard to the limitations of instant claims 1, 11 and 19-20, Haddleton discloses a production of an aqueous polymer emulsion comprises a low molecular weight polymer containing acid-functional groups made by using a free-radical polymerization process which employs a free-radical initiator and, for the purpose of controlling molecular weight, a transition metal chelate complex, wherein said low molecular weight polymer has a number average **molecular weight within the range of from 500 to 50,000** (abstract).

Typically the acid-bearing comonomers are olefinically unsaturated carboxyl-functional monomers such as mono carboxyl-functional acrylic monomers and

olefinically unsaturated dicarboxyl bearing monomers; examples include **acrylic acid, methacrylic acid**, itaconic acid, maleic acid and fumaric acid (col. 5, lines 41-46). Non-acid functional monomer(s), which may be copolymerized with the acid monomer(s) include alkylmethacrylates and styrenes, and alkylacrylates can also be used, particularly if included as **comonomers** at low levels. Typically, the acid functional low molecular weight polymer is derived from a monomer system which contains **1-60 weight % of acid comonomer(s)**, and correspondingly **99-40 weight % of non acid functional comonomer(s)** (col. 6,lines 17-23). The low molecular weight polymer should have a number average molecular weight within the range of from **500-50,000**, preferably 700-20,000 and particularly 1,000-10,000 (col. 7, lines 8-10).

Haddleton discloses an aqueous emulsion polymerization process to form an aqueous emulsion of a hydrophobic polymer from at least one olefinically unsaturated monomer, wherein the low molecular weight polymer is introduced to the aqueous medium of said emulsion polymerization process before the start of and/or during said emulsion polymerization process and becomes dissolved or dispersed in said aqueous medium (abstract). The polymerization process can be carried out in the presence of a polymerization medium (acting as a **carrier medium** for the components and as a heat transfer medium) or in the absence of such a medium (i.e. in bulk) (col. 4, lines 21-24).

Haddleton does not disclose that it is possible to obtain the polymer composition without transition metal complexes.

Rehmer discloses a process for producing readily filterable and deodorizable, highly concentrated, aqueous dispersions of pressure-sensitive adhesive, having readily

reproducible properties, on the basis of copolymers of esters of acrylic and/or methacrylic acid, by emulsion polymerization in the presence of customary emulsifiers and free-radical polymerization initiators in accordance with the monomer emulsion feed polymerization technique, in which the monomer emulsion is run in a feed stream into the polymerization reactor, which comprises conducting the emulsion polymerization of a monomer mixture comprising (A) at least 50% by weight of the overall monomer amount of at least one ester of acrylic and/or methacrylic acid with alcohols of 1 to 18 C atoms and (B) other olefinically unsaturated monomers (col. 2, lines 22-37).

This polymer composition does not contain transition metal complexes.

Therefore, it would have been obvious to one having ordinary skill in the art when the invention was made to employ emulsion polymerization in the presence of customary emulsifiers and free-radical polymerization initiators in accordance with the monomer emulsion feed polymerization technique without transition metal complexes as taught by Rehmer in order to obtain the polymer composition comprising methacrylic acid units and alkyl esters of methacrylic acid units with low molecular weight as taught by Haddleton, to avoid the using of transition metal chelate complex, and thus to arrive at the subject matter of claim 1 and dependent claims 11, 19 and 20.

With regard to the limitations of instant claims 1 and 6-7, the combined teaching of Haddleton and Rehmer does not disclose that pH-sensitive polymer brings about at least 60% haemolysis at pH 5.5, and less that 5% haemolyses at pH 7.4, at a concentration of 150 g/ml in a cytotoxicity test with human red blood cells.

Regarding the pH-sensitive polymer's limitations in view of substantially identical monomers, their weight ratio, initiators (peroxide, redox, azo compounds, such as 2,2'-azobis isobutyronitrile, etc.), emulsifier (sodium lauryl sulphate), process of aqueous emulsion polymerization producing such polymers and the same range of molecular weight (compare US'632, col. 12, line 7 through col. 17, line 18 and specification, page 14, line 15 through page 16, line 22) being used by Haddleton and Rehmer and the applicant, it is the examiner position to believe that the instantly claimed product , i.e. pH-sensitive polymer of Haddleton and Rehmer is substantially the same as pH-sensitive polymer recited in claim 1, even though obtained by a different process, consult ***In re Thorpe,*** 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

With regard to the limitations of instant claims 2-5, Haddleton discloses that methacrylates include normal or branched alkyl esters of C1 to C12, especially C1 to C10, alcohols and methacrylic acid, (i.e. C1 to C12, especially C1-10, alkyl methacrylates) such as **methyl methacrylate, ethyl methacrylate, n-butyl methacrylate** and lauryl methacrylate. Acrylates include normal and branched alkyl esters of C1 to C12, especially C1 to C10, alcohols and acrylic acid, (i.e. C1-C12, especially C1-10, alkyl acrylates) such as **methyl acrylate, ethyl acrylate, n-butyl acrylate** and 2-ethylhexyl acrylate (col. 5, lines 53-67). There is a mixture of MMA (mehyl methacrylate), BMA (butyl methacrylate) and MAA (methacrylic acid) used for the preparation of the copolymer in LMP 10 (low molecular weight polymer) (col. 16 line 65 through col. 17, line 13).

Therefore all of the above methacrylates and acrylates are subgenus of non-acid functional monomers, which are generically disclosed, and which are polymerized with acid monomer(s). Therefore, they can substitute each other. Additionally, according to the example of LMP 10, they can be employed singly or two or more monomers.

It is further noted that the amount of methacrylic acid, methacrylates and acrylates in the copolymer is a result effective variable, and therefore, it is within the skill of those skilled in the art to find the optimum value of a result effective variable, as per ***In re Boesch and Slaney*** 205 USPQ 215 (CCPA 1980). See also *Peterson*, 315 F.3d at 1330, 65 USPQ2d at 1382: "The normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages."

With regard to the limitations of instant claims 8-10, it is worth to mention that these claims are intended use of pH-sensitive polymer and therefore it would have been known to one having ordinary skill in the art when the invention was made how to use the polymer composition in pharmaceutical industry.

Furthermore Haddleton discloses that one or both of the low molecular weight polymer and the hydrophobic polymer possess functional groups for **imparting latent crosslinkability to the composition** (i.e. so that crosslinking takes place e.g. after the formation of a coating therefrom). Alternatively, one or both polymers could carry functional groups such as hydroxyl groups and the composition subsequently formulated with a **crosslinking agent** such as a polyisocyanate, melamine, or glycouril; or the functional groups on one or both polymers could include keto or aldehyde

carbonyl groups and the subsequently formulated crosslinker could be a polyamine or polyhydrazide such as adipic acid dihydrazide (col. 11, lines 10-27).

With regard to the limitations of instant claim 12, Haddleton does not disclose that molecular weight regulator is dodecyl mercaptan and/or 2-ethylhexyl thioglycolate.

Rehmer discloses that in the polymerization reaction it is also possible to add regulators, especially in amounts of up to 0.5% by weight of the amount of monomers, which reduce the degree of polymerization of the resulting **emulsion polymers**. Examples of such regulators are mercaptans, such as tert-**dodecyl mercaptan**, **ethylhexyl thioglycolate**, or 3-mercaptopropyltrimethoxysilane, or unsaturated compounds with allylic hydrogens, such as butenol (col.3, lines 31-38).

Therefore, it would have been obvious to one having ordinary skill in the art when the invention was made to incorporate dodecyl mercaptan and/or 2-ethylhexyl thioglycolate as molecular weight regulators for emulsion polymers as taught by Rehmer in Haddleton's pH-sensitive polymer composition in order to obtain the polymer composition comprising methacrylic acid units and alkyl esters of methacrylic acid units with low molecular weight as taught by Haddleton, and thus to arrive at the subject matter of claim 1 and dependent claim 12.

(10) Response to Argument

Regarding the Applicants arguments that if methacrylic acid is an acid comonomer, and if alkyl esters of (meth) acrylic acid are non acid functional comonomers, these ranges would appear to overlap the monomer content ranges of

Claim 1, it is noted that the rejection was made not under 35 U.S.C. § 102 but not under 35 U.S.C. § 103(a) because "[A]nticipation under § 102 can be found only when the reference discloses exactly what is claimed and that where there are differences between the reference disclosure and the claim, the rejection must be based on § 103 which takes differences into account." *Titanium Metals Corp. v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985).

Therefore it is within the skill of those skilled in the art to find the optimum value of a result effective variable, as per ***In re Boesch and Slaney*** 205 USPQ 215 (CCPA 1980).

In response to the Applicants arguments that Rehmer discloses a process for producing copolymers of acrylic and/or (meth)acrylic acid by emulsion polymerization instead of by CCT process used by Haddleton, and the obviousness rejection is based on substituting the emulsion polymerization method of Rehmer for the CCT process of Haddleton for the purpose of obtaining the polymers of the invention which do not contain transition metal complexes, it is worth to mention that instant claim 1 is a product claim and it recites a pH-sensitive polymer, but not a process for preparing a pH-sensitive polymer, therefore, it is the examiner position to believe that the instantly claimed product , i.e. pH-sensitive polymer of Haddleton and Rehmer is substantially the same as pH-sensitive polymer recited in claim 1, even though obtained by a different process, consult ***In re Thorpe,*** 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

It appears that the focal argument resides in the contention that there is no motivation for selecting polymers which brings about at least 60% haemolysis at pH 5,5 and less than 5% haemolysis of human red blood cells at pH 7.4, the rejection was made in the sense of ***In re Spada***, 911 F 2d 705, 709 15 USPQ 1655, 1658 (Fed. Cir. 1990), which settles that **when** the claimed compositions **are not novel**, they are not rendered patentable by recitation of properties, whether or **not** these properties are shown or suggested in prior art.

Therefore, the properties governing the claimed composition comprising brings about at least 60% haemolysis at pH 5,5 and less than 5% haemolysis of human red blood cells at pH 7.4, at a concentration of 150 µg/ml in a cytotoxicity test with human red blood cells, are inherently the same as or rendered obvious over Haddleton and Rehmer, since Haddleton and Rehmer's polymer contains essentially the same methacrylic acid units and esters of methacrylic acid, as instantly claimed and their weight ratio, initiators, emulsifier, process of aqueous emulsion polymerization producing such polymers and the same range of molecular weight, etc.

Since the USPTO does not have proper equipment to do the analytical test the burden is now shifted to the applicant to prove otherwise. ***In re Best***, 195 USPQ 430, (CCPA 1977).

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Michael M. Bernshteyn

Conferees:

Romulo Delmendo

David Wu